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Allie Barrett

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PATENT & TRADEMARK OFFICE

Applicant:	Van Tassel, et al.
Serial No.:	09/382,275
Filed:	August 25, 1999
Title:	**IMPLANTABLE DEVICE FOR PROMOTING REPAIR OF A BODY LUMEN**
Examiner:	Hieu Phan
Group Art Unit:	3738
Atty. Docket No. :	20220-311

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

NEW APPEAL BRIEF UNDER 37 CFR 41.37

Mail Stop Appeal Brief-Patents
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Sir:

In response to the Notification of Non-Compliant Appeal Brief under 37 CFR 41.37(c)(1)(v), the Applicant has amended the section entitled Summary of Claimed Subject Matter to include distinct descriptions for claims 1 and 58.

In response to the Final Office Action dated August 11, 2004, please consider the Appeal Brief contained herein. It is believed that this Appeal Brief addresses all outstanding issues; that entry of this Appeal Brief is proper; and that the preparation and mailing of an Examiner's Answer is now in order.

Please also correct our Attorney Docket Number from MEDIV1120-1 to **20220-311**.

Real Party in Interest

The real party in interest is TriCardia, LLC, a Minnesota corporation having a place of business at 6420 Bayview Place, Excelsior, Minnesota 55331. TriCardia, LLC is the Assignee of all rights in the application.

Related Appeals and Interferences

There are currently no appeals or interferences known to the appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1, 2, 30, 43-45, 58-64, 73 and 82-87 are currently pending and of these claims, claims 1 and 58 are independent. Claims 3-29, 31-42, 46-57, 56-72, and 74-81 have been previously withdrawn from consideration.

Status of Amendments

No amendments have been filed subsequent to final rejection. The claims as they are currently entered are presented in the Appendix of this document.

Summary of Claimed Subject Matter

The claims appealed in this Appeal, namely claims 1, 2, 30, 43-45, 58-64, 73 and 82-87, stand or fall together. Specifically, claims 1 and 58 are independent and the remaining claims depend from either of these two claims.

In accordance with 37 C.F.R. 41.37(c)(1)(v) the subject matter of independent claims 1 and 58 is concisely explained below. It is believed that neither of these independent claims include means plus function or step plus function wording.

The subject matter as defined in claim 1 involved in this appeal relates to "a tubular stent body...having surface features sized and/or arranged to promote an organized growth pattern of infiltrating cells" pg 5, ln 19-20. "Further the surface features in the stent body are selected to cause to living cells that infiltrate and populate

the stent to undergo cell growth in a specific pattern determined by the placing and dimensions of the surface features of the stent body" pg 7, lns 5-12.

One embodiment of the stent of claim 1 is disclosed in the application in Figure 2 and on page 18, lines 7-18:

> ...metal stents are formed of a material comprising metallic fibers uniformly laid to form a three-dimensional non-woven matrix and sintered to form a labyrinth structure exhibiting high porosity, typically in a range from about 50 percent to about 85 percent, preferably at least about 70 percent. The metal fibers typically have a diameter in the range from about 1 micron to 25 microns. The average effective pore size is in the stent body such that cellular ingrowth into the pores and interstices is enhances, for example having an average diameter in the range from about 30 microns to about 65 microns. Pg 18, lns 7-18.

In this respect and with reference to the citations in the specification as set forth above, the subject matter of claim 1 is directed to a tubular stent body having a plurality of interconnected microholes distributed throughout said stent body substantially uniformly along the entire length of said stent body, said plurality of microholes being sufficiently small so as to promote an organized growth pattern of infiltrating cells throughout said stent body, said stent body being otherwise substantially free of holes larger than said microholes.

The present invention as defined in claim 58 involved in this appeal relates to a method of treating a tubular body organ of a subject and includes promoting the ingrowth of living cells in "a tubular stent body...having surface features sized and/or arranged to promote an organized growth pattern of infiltrating cells" pg 5, ln 19-20. "Further the surface features in the stent body are selected to cause to living cells that infiltrate and populate the stent to undergo cell growth in a specific pattern determined by the placing and dimensions of the surface features of the stent body" pg 7, lns 5-12.

In one embodiment of the method of claim 58, a stent such as the stent disclosed in the application in Figure 2 and on page 18, lines 7-18 is used:

> ...metal stents are formed of a material comprising metallic fibers uniformly laid to form a three-dimensional non-woven matrix and sintered to form a labyrinth structure exhibiting high porosity, typically in a range from about 50 percent to about 85 percent, preferably at least about 70 percent. The metal fibers typically have a diameter in the range from about 1 micron to 25 microns. The average effective pore size is in the stent body such that cellular ingrowth into the pores and interstices is enhances, for example having an average diameter in the range from about 30 microns to about 65 microns. Pg 18, lns 7-18.

As further described on page 21, lines 16-20 in one embodiment of the invention of claim 58, "the stent of the present invention can be implanted using any surgical technique known in the art as is dictated by the particular tubular body organ to be treated. However, it is presently preferred to implant the invention living stent by placing the device in an unexpanded form over a deflated balloon on the distal end of an intravascular catheter."

In this respect and with reference to the specification as set forth above, the subject matter of claim 58 is directed to a method for treating a tubular body organ in a subject in need thereof where the method comprises promoting the ingrowth of living cells in a stent having a plurality of interconnected microholes distributed within the stent body substantially uniformally along the entire length of the stent body, the plurality of microholes being sufficiently small in size so as to promote ingrowth of the cells, and the stent body being otherwise substantially free of holes larger than the microholes and implanting the stent into the tubular organ of the subject prior to or following the promoting of the ingrowth of the living cells so as to treat the tubular organ.

Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed on appeal is the Examiner's rejection of claims, 1, 2, 30, 43-45, 58-64, 73 and 82-87 under 35 U.S.C. Section 112, 1st Paragraph. The Examiner contends that these claims do not conform to the written description requirement.

Argument

Claims 1, 2, 30, 43-45, 58-64, 73 and 82-87 are rejected under 35 U.S.C. Section 112, 1st Paragraph, on grounds that they do not conform with the written description requirement. In particular, the Examiner asserts that "the original disclosure lacks any description of an embodiment which is substantially free of the holes larger than the microholes". Applicants hereby appeal this rejection. Applicants further submit that the rejection is improper and that the Examiner's rejection should be reversed and the claims allowed. The reasons for reversal are set forth below.

I. Background

In an in-person interview with the Examiner that occurred on February 19, 2004, the Examiner agreed that certain amendments to independent claims 1 and 58 would overcome the prior art rejection asserted at that time.[1] There was no indication at the interview of any other issues associated with the claims (with the exception of a prior art update search). Those proposed claim amendments were then formally presented to the Examiner in an Amendment filed April 12, 2004.

Consistent with the agreement reached at the interview, the Examiner declined to assert the prior art rejection in the Final Office Action dated August 11, 2004 (and no additional prior art rejection was made based on the updated search). However, the Examiner raised a new rejection in the Final Office Action, this time based on the written description requirement of 35 U.S.C. Section 112, first paragraph.

[1] The interview on February 19, 2004 was the second of two in-person interviews that have occurred in this application, the first occurring on September 24, 2002. Each interview involved the identical prior art rejection. And each interview resulted in agreement that the prior art rejection was overcome by certain proposed claims only to be followed by yet another rejection in a subsequent office action.

This rejection (which is the subject of this Appeal) was quite disappointing since the subject matter added to the claims in conformance with the agreement reached at the interview on February 19, 2004 simply clarifies what has long been recited and argued in this application for the last two and ½ years and never, until now, with any Section 112 issues raised by the Examiner. The inventors are at a loss to understand this rejection given the lengths the inventors have gone to meet with the Examiner and respond to all issues in a timely fashion.

II. Response to the Rejection

In response to the rejection and with reference to independent claims 1 and 58, the Board is first directed to page 18, lines 1-4 of the originally filed application, where it is stated:

> Stent 14 is preferably a balloon expandable device made of expandable metal or braided wire, but also may be designed as a self-expanding structure. *It may also be fabricated from a composition of metallic fibers, **uniformly** laid to form a three dimensional, non-woven structure, such as is shown in Figure 2.* (emphasis added).

The Board is further directed to page 15, lines 8-15 of the originally filed application, where it is stated:

> Preferred metal stents are formed of a material comprising metallic fibers ***uniformly** laid to form a three-dimensional non-woven matrix and sintered to form a labyrinth structure exhibiting high porosity, typically in a range from about 50 percent to about 85 percent, preferably at least about 70 percent*. The metal fibers typically have a diameter in the range from about 1 micron to 25 microns. The average effective pore size is *in the stent body* such that cellular ingrowth into the pores and interstices is enhanced, for example having an average diameter in the range from about 30 microns to about 65 microns. (emphasis added).

These two citations (which include both text AND and a drawing figure) demonstrate that the application as originally filed clearly contemplated an embodiment supportive of claims 1 and 58. The citations show a stent of ***uniformly*** laid metallic fibers that create tiny pores and interstices ***in the stent body***. This can mean nothing other than an embodiment of "a stent having a plurality of interconnected microholes distributed throughout said stent body substantially uniformally along the entire length of said stent body, said plurality of microholes being sufficiently small so as to promote an organized growth pattern of infiltrating cells throughout said stent body." (claims 1 and 58). And most importantly, these citations clearly mean a stent body that is "otherwise substantially free of holes larger than said microholes."[2]

Yet these two citations are not the sole support found in the originally filed application. Further support is present at page 6, lines 7-10 and page 15, line19 through page 16, line 4 which also describe an embodiment of the claimed stent. The only difference is that, unlike the citations above, this embodiment involves a ***stent body*** made from a porous polymer as opposed to ***stent body*** made from a matrix of metallic fibers. But this distinction is immaterial as to the issue at hand since the basic configuration of the stent is the same in each embodiment and the claims are generic to both embodiments in any event.

Lastly, reference is made to page 6 line 28, where it is expressly disclosed that one embodiment of the invention is one in which the "stent body is itself formed of a fibrous mesh". Such a fibrous mesh similarly supports the invention as claimed, particularly as to the phrase "otherwise substantially free of holes larger than said microholes".

In rebuttal to the evidence presented above, the Examiner focuses on one drawing figure of the application, namely Figure 1, and asserts that this drawing figure alone somehow limits or "trumps" the written description of other embodiments of the invention as noted above. Figure 1 does indeed disclose a stent body that has holes

[2] Indeed, the only reason that the "otherwise substantially free of holes larger than said microholes" phrase was added was to clarify (at the Examiner's request) that the microholes were "distributed throughout said stent body substantially uniformally along the entire length of said stent body."

that are larger than the microholes. This fact, however, is irrelevant because the primary purpose of Figure 1 is to provide written description for the use of a temperature monitor in any kind of stent (including one with holes larger than microholes) not just for the inventive stent claimed herein. Indeed, as stated previously, when it comes to the drawing figures of the application, it is Figure 2 that supports the claimed invention. And in this regard, it is the description of Figure 2 on page 10, lines 12-13 that shows that a stent "like that shown in Figure 1" could be replaced with a stent as claimed (i.e., a stent with a "stent body that is otherwise substantially free of holes larger than said microholes").

In view of the foregoing, the rejection of the claims based on 35 U.S.C. Section 112, first paragraph is incorrect. The Specification of the application is replete with written description sufficient to support the claims. Accordingly, the Examiner's rejection should be reversed and the allowability of the claims indicated.

III. Response to Other Comments by Examiner

A. *"Support" Citations*

The Examiner has asserted that the Applicant failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations, citing MPEP 714.02. First, it is submitted that the Examiner is simply incorrect.

The Amendment filed April 11, 2004, introduced new claims 83 and 86 each of which included the new recitation at issue in the current Section 112 rejection (by virtue of their dependency to claims 1 and 58, respectively). In doing so, the Applicants specifically directed the Examiner to page 15, line 9 of the original application as providing the requisite support for the claimed invention. This citation is the very same citation discussed above that clearly shows support for the claimed invention, including the recitation now at issue.

Second, it is noted that the recitation at issue in the current rejection is a recitation that was added at the suggestion of the Examiner in the interview on February 19, 2004 to clarify ***existing*** claim language. Moreover, at no time was the existing claim

language ever previously questioned (either formally in an office action or informally in an interview) under 35 U.S.C. Section 112.

B. *New Matter under M.P.E.P. 2163.06*

The Examiner seems to intimate that a prior art rejection may yet be applicable in light of the provisions of MPEP 2163.06. However, this portion of the MPEP pertains to new matter and no new matter has been added either in this response or at any time previous to this Response. Hence, M.P.E.P. Section 2163.06 should not apply in any way to the claims as currently pending.

C. *"Relative" Language Under M.P.E.P. 2173.05(b)*

The Examiner makes reference to M.P.E.P. 2173.05(b) apparently in reference to the usage of the term "substantially" in the claims. In this regard, it is first noted that the term "substantially" has been present in claims 1 and 58 for well over a year and no exception has been taken to this term in at least two previous reviews of the claims.

Second, the specification as originally filed is replete with a description of microhole sizes and porosity values across a stent body in accordance with the claimed invention as it relates to the term "substantially". See for example, the originally filed specification at page 11, lines 25-26; page 12, lines 12-13; page 15, lines 8-18; and, page 15, lines 24-26. Clearly this disclosure in the specification provides the requisite general guidelines necessary to ensure the definiteness of the claim. See, *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). Moreover, these portions of the specification also clearly lead one of ordinary skill in the art to know the scope of the claim, especially given the high level of skill (e.g., interventional cardiologists) associated with those involved in this art. See, *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

IV. Conclusion

For at least all the reasons stated herein, it is submitted that the Examiner's rejection is erroneous. As a result, the Applicant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

Respectfully submitted,

Dated: Aug 12, 2005

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Claims Appendix

1. (Previously Presented) An implantable stent comprising a tubular stent body having a plurality of interconnected microholes distributed throughout said stent body substantially uniformally along the entire length of said stent body, said plurality of microholes being sufficiently small so as to promote an organized growth pattern of infiltrating cells throughout said stent body, and said stent body being otherwise substantially free of holes larger than said microholes.

2. (Original) The stent according to claim 1 wherein the organized growth pattern is angiogenesis.

3. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a plurality of depressions in the surface of at least a portion of the stent body.

4. (Withdrawn) The stent according to claim 3 wherein the depressions have an average volume per depression in the range from about 10 μm to about 100 μm.

5. (Withdrawn) The stent according to claim 3 wherein the depressions are in a regular pattern on at least the interior surface of the stent body.

6. (Withdrawn) The stent according to claim 5 wherein the pattern is a waffle weave.

7. (Withdrawn) The stent according to claim 5 wherein the pattern is selected to create turbulence in the flow of fluid through the stent body.

8. (Withdrawn) The stent according to claim 7 wherein the turbulence increases fluid shear stress upon the infiltrating cells.

9. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a plurality of longitudinal pleats, grooves or channels in the stent body.

10. (Withdrawn) The stent according to claim 9 wherein the pleats, grooves, or channels have an average height or depth in the range from about 10 μm to about 100 μm and an average distance from center to center in the range from about 10 μm to about 100 μm.

11. (Withdrawn) The stent according to claim 9 wherein the pleats, grooves, or channels are spaced and sized to promote create fluid shear stress in flow of blood through the stent and/or to cause alignment of cells that infiltrate the pleats, grooves, or channels.

12. (Withdrawn) The stent according to claim 1 wherein the surface features comprise pores in the stent body having an average diameter in the range from about 30 microns to about 65 microns.

13. (Withdrawn) The stent according to claim 12 wherein the stent body is formed from a polymer or a non-woven matrix of metal fibers.

14. (Withdrawn) The stent according to claim 13 wherein the metal fibers are stainless steel, tantalum, elgiloy, nitinol, or a suitable combination thereof, and have a diameter in the range from about 1 micron to 25 microns.

15. (Withdrawn) The stent according to claim 13 wherein the non-woven matrix has a porosity of about 50% to about 85%.

16. (Withdrawn) The stent according to claim 15 wherein the porosity is at least about 70%.

17. (Withdrawn) The stent according to claim 1 wherein the surface features comprise an array of upstanding projections that promote shear turbulence in blood flow along at least a portion of the surface of the stent body.

18. (Withdrawn) The stent according to claim 17 wherein the projections have an average height of from about 10 μm to about 100 μm.

19. (Withdrawn) The stent according to claim 18 wherein the projections are an orderly array of hooks or stalks having a diameter to height ratio of from about 10:1 to about 100:1.

20. (Withdrawn) The stent according to claim 19 wherein the hooks or stalks have a uniform spacing of from about 10 μm to about 200 μm from center to center.

21. (Withdrawn) The stent according to claim 1 wherein the stent body is formed of a polymeric material having pores with an average pore diameter in the range from about 30 microns to about 65 microns.

22. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a layer of a biocompatible substance that expands or thickens in an aqueous environment to assume a three-dimensional form, wherein the layer covers at least a portion of the surface of the stent body.

23. (Withdrawn) The stent according to claim 22 wherein the three dimensional form comprises an array of upstanding projections.

24. (Withdrawn) The stent according to claim 22 wherein the layer comprises a hydrogel.

25. (Withdrawn) The stent according to claim 22 wherein the three dimensional form is porous.

26. (Withdrawn) The stent according to claim 22 wherein the expandable substance is a hydrogel.

27. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a pattern of hydrogel markings on at least a portion of the surface of the stent body.

28. (Withdrawn) The stent according to claim 27 wherein the pattern of markings comprises a plurality of dots, lines, curvilinear tracings, or a mixture thereof.

29. (Withdrawn) The stent according to claim 28 wherein the markings are distributed over the interior surface of the stent body.

30. (Original) The stent according to claim 1 wherein the stent is diametrically adjustable.

31. (Withdrawn) The stent according to claim 1 wherein the stent further comprises a transcutaneously energized heating mechanism attached to the stent body.

32. (Withdrawn) The stent according to claim 31 wherein the heating mechanism is adapted to controllably heat the stent to temperatures from about 38° C to about 49° C when the stent is implanted.

33. (Withdrawn) The stent according to claim 32 wherein the heating mechanism comprises a thermostat/heat regulator.

34. (Withdrawn) The stent according to claim 33 wherein the thermostat/heat regulator comprises one or more heat sensors and telemetering device for conveying the temperature sensed by each sensor.

35. (Withdrawn) The stent according to claim 34 wherein the telemetering device comprises an antenna coil wrapped about the surface of the stent and a hybrid integrated circuit chip in communication with the antenna coil, whereby energy picked up by the antenna coil powers the hybrid circuit.

36. (Withdrawn) The stent according to claim 34 wherein the thermostat/heat regulator comprises at least two heat sensors located at opposite ends of the stent body.

37. (Withdrawn) The stent according to claim 35 wherein the heat sensors have sufficient sensitivity to detect a temperature difference as small as 0.1° C from one end of the stent to the other end.

38. (Withdrawn) A stent system comprising a stent according to claim 1 in spaced juxtaposition to an energy source for transcutaneously applying energy to the stent, thereby causing the temperature of the stent to increase to a temperature above body temperature.

39. (Withdrawn) The stent system according to claim 37 wherein the energy source delivers electromagnetic energy to the stent in the form of radio frequency energy, microwave energy, or a magnetic field.

40. (Withdrawn) A stent system comprising a stent according to claim 37 in spaced juxtaposition to an energy source for transcutaneously applying energy to the

stent, thereby causing the temperature of the stent to increase to the temperature from about 38° C to about 49° C.

41. (Withdrawn) The stent system according to claim 35 wherein each of the sensors produces a temperature output signal corresponding to the temperature sensed and wherein the stent system further comprises a monitor in spaced juxtaposition to the stent for transcutaneously receiving the output signal from each sensor.

42. (Withdrawn) The stent system according to claim 39 wherein the monitor is in communication with the energy source and signals from the monitor activate the energy source.

43. (Previously Presented) An active stent comprising a stent according to claim 1 and further comprising live cells growing in said interconnected microholes.

44. (Previously Presented) The active stent according to claim 43 wherein the live cells are selected from the group consisting of endothelial cells, smooth muscle cells, leukocytes, monocytes, epithelial cells, polymorphonuclear leukocytes, lymphocytes, basophils, fibroblasts, stem cells, epithelial cells and eosinophils.

45. (Previously Presented) The active stent according to claim 44 wherein the live cells are smooth muscle cells, epithelial cells, or endothelial cells.

46. (Withdrawn) The active stent according to claim 43 wherein the stent further comprises a transcutaneously energized heating mechanism adapted to control the heating of the stent to a temperature sufficient to cause the live cells to increase production of one or more bioactive agents.

47. (Withdrawn) The active stent according to claim 46 wherein the bioactive agent stimulates angiogenesis and/or capillary formation.

48. (Withdrawn) The active stent according to claim 47 wherein the bioactive agent is vascular endothelial growth factor (VEGF), a fibroblast growth factor (FGF), angiopoietin 1, or thrombin.

49. (Withdrawn) The active stent according to claim 46 wherein the bioactive agent modifies vascular structure in the hematologic system.

50. (Withdrawn) The active stent according to claim 49 wherein the bioactive agent modifies platelet function.

51. (Withdrawn) The active stent accorgin to claim 46 wherein the bioactive agent is an anti-proliferative, anti-restenotic, or apoptotic agent.

52. (Withdrawn) The active stent according to claim 51 wherein the bioactive agent is nitric oxide.

53. (Withdrawn) The active stent according to claim 46 wherein the agent increases production of nitric oxide in the cells in or around the stent.

54. (Withdrawn) The active stent according to claim 43 further comprising means carried by the stent body for telemetering stent temperature information to an external energy source.

55. (Withdrawn) An implantable stent comprising a tubular stent body and a heating mechanism attached to the stent body that includes one to about six temperature sensors attached at discrete spaced locations along the length thereof, each adapted for sensing the temperature of the stent at the discrete location, and a telemetering device for transcutaneously transmitting the output of the temperature sensors to an external monitor; wherein the stent body comprises metal or a dielectric substance.

56. (Withdrawn) The stent according to claim 55 wherein two of the temperature sensors are located at opposite ends of the tubular stent body.

57. (Withdrawn) The stent according to claim 55 wherein the temperature sensors are sensitive to temperature differences as small as 0.1° C.

58. (Previously Presented) A method for treating a tubular body organ in a subject in need thereof said method comprising:

promoting the ingrowth of living cells in a stent having a plurality of interconnected microholes distributed within said stent body substantially uniformally along the entire length of said stent body, said plurality of microholes being sufficiently small in size so as to promote ingrowth of the cells, and said stent body being otherwise substantially free of holes larger than said microholes, and,

implanting the stent into the tubular organ of the subject prior to or following the promoting of the ingrowth of the living cells so as to treat the tubular organ.

59. (Original) The method according to claim 58 wherein the living cells are donor or autologous cells.

60. (Original) The method according to claim 59 wherein the living cells are autologous.

61. (Original) The method according to claim 58 wherein the treatment further comprises promoting or inhibiting angiogenesis within the stent body.

62. (Original) The method according to claim 58 wherein the body organ is a blood vessel.

63. (Original) The method according to claim 58 wherein the treating comprises holding the cells in a specific pattern or stimulating the growth of the cells into an organized growth pattern.

64. (Original) The method according to claim 63 wherein the organized growth pattern develops into an organized cellular structure within the stent body.

65. (Withdrawn) The method according to claim 58 wherein the stent can be heated by transcutaneously applied energy and the method further comprises transcutaneously energizing the heating of the stent to a temperature above normal body temperature sufficient to cause the living cells to express one or more bioactive agents.

66. (Withdrawn) The method according to claim 65 wherein the one or more bioactive agents promotes or inhibits angiogenesis within the living cells growing in the stent.

67. (Withdrawn) The method according to claim 65 wherein at least some of the living cells contain a DNA construct encoding and expressing a bioactive agent under the control of an operatively associated exogeneous heat shock promoter.

68. (Withdrawn) The method according to claim 67 further comprising turning the promoter on or off by controlling the heating of the stent.

69. (Withdrawn) The method according to claim 65 wherein the temperature to which the stent body is heated remains below a value lethal to the living cells.

70. (Withdrawn) The method according to claim 69 wherein the temperature to which the stent body is heated is in a range from about 38° C to about 49° C.

71. (Withdrawn) The method according to claim 67 wherein the heat shock promoter is derived from *E. Coli or Drosophilia.*

72. (Withdrawn) The method according to claim 67 wherein the treating further comprises chronically releasing the bioactive agent on demand by transcutaneously energizing the stent.

73. (Original) The method according to claim 58 wherein the living cells are endothelial cells, smooth muscle cells, leukocytes, monocytes, polymorphonuclear leukocytes, lymphocytes, basophils, fibroblasts, stem cells, epithelial cells or eosinophils.

74. (Cancelled)

75. (Cancelled)

76. (Withdrawn) A method for measuring flow of a fluid through a body lumen, said method comprising:

implanting a stent according to claim 34 into a body lumen having a flow of fluid therethrough,

energizing the implanted stent transcutaneously to raise the temperature thereof above body temperature,

monitoring transcutaneously the output from one or more of the temperature sensors upon cessation of the energizing to determining the cooling rate at each of the one or more sensors, and

obtaining the flow rate of the fluid through the stent from the cooling rate at the one or more sensors.

77. (Withdrawn) The method according to claim 76 wherein the temperature of the stent is raised from 0.1° C about 12° C above body temperature.

78. (Withdrawn) The method according to claim 76 wherein the fluid is blood and the stent is implanted in a blood vessel.

79. (Withdrawn) The method according to claim 76 wherein the cooling rate is determined at least two of the sensors and the flow rate is obtained as a function of the distance between the two sensors.

80. (Withdrawn) The method according to claim 76 wherein the cooling rate is determined using the temperature difference between at least two of the temperature sensors.

81. (Withdrawn) The method according to claim 76 wherein the method is repeated periodically to monitor occlusion of the lumen.

82. (Previously Presented) The stent according to claim 1, wherein said stent body is penetrated with said microholes.

83. (Previously Presented) The stent according to claim 1, wherein said stent body is formed from a three dimensional non-woven matrix.

84. (Previously Presented) The stent according to claim 1, wherein said microholes extend throughout said stent body so as to promote cell growth outward into said stent tube and into attachment with cells at either end of said stent.

85. (Previously Presented) The method according to claim 58, wherein said stent body is penetrated with said microholes.

86. (Previously Presented) The method according to claim 58, wherein said stent body is formed from a three dimensional non-woven matrix.

87. (Previously Presented) The method according to claim 58, wherein after the implanting of said stent, said ingrowth of living cells is promoted such that said cells grow outward into said stent tube and into attachment with cells at either end of said stent.